Product Design Specifications for BME 301 Group 8: Measurement of tibial translation in dogs with anterior cruciate ligament rupture (tibial_measurement)

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Problem Statement:

Arthritis in canines often leads to joint degeneration and rupture of the Anterior Cruciate Ligament (ACL). Diagnosis of this condition is often difficult because the current methods used are non-quantitative. The aim of this project is to quantify the amount of tibial translation in a canine's leg caused by a known applied force in order to determine the severity of an ACL rupture. Preliminary parts for a device that can accomplish this have been developed and it is the goal of this team to create and test a working model.

1. Design Requirements:

The device must meet all of the client requirements

- a. Performance Requirements: The device must be able to secure to the anatomical landmarks of a canine's leg and measure the amount of displacement in the tibia effectively. The Hall effect sensor and magnet system must stay in the same plane during the measurement.
- b. Safety: The device should not cause any serious harm to a canine's leg.
- c. Accuracy and Reliability: Data obtained from testing should be repeatable so that the device may be accurate when used in clinical testing. Hall effect sensor should be accurate at 15V of input voltage.
- d. Life in Service: The device should last for 10 years.
- e. Shelf life: The device should have a shelf life of 5 years.
- f. Operating environment: The device should withstand room temperature and be easily cleanable so that it can be as sterile as possible.
- g. Ergonomics: A trained veterinarian should operate the device.
- h. Size: The device should not be big so that it will not cause injury to the canine.
- i. Weight: The device must not weigh more than 15 grams.
- j. Materials: The device must be made of sterile and lightweight materials so that the canine will not be injured when the ACL rupture test is performed with the device.
- k. Aesthetics, Appearance, Finish: The device must have an internalized system to increase accuracy.

- 2. Production Characteristics:
- a. Quantity: One working unit is necessary to quantify tibial translation.
- b. Target Product Cost: As cheap as possible for mass-production.
- 3. Miscellaneous:
 - a. Standards and Specifications: Approval from a medical organization.
 - b. Customer: Veterinarians should be able to use this easily.
 - c. Patient-Related Concerns: The device should be sterile and the system must be properly internalized so the canine is not caused any harm.
 - d. Competition: The model is similar to an arthrometer for humans. X-ray is a good qualitative method but it is expensive and non-quantitative.